UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,

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Plaintiff,

v. : Civil Action No.

05 CV 11805 NMG

RICHARD F. SELDEN,

.

Defendant.

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR ENTRY OF FIVE-YEAR BAR ORDER

Plaintiff, the Securities and Exchange Commission ("SEC"), herby submits this memorandum in support of its motion for entry of an order barring defendant Richard F. Selden from serving as an officer or director of a public company for five years.

SUMMARY

On July 8, 2008, the Court entered a final judgment by consent. Paragraph V of the final judgment provides that the Court will determine whether to enter an order barring Selden from serving as an officer or director of a public company. As set forth below, the Commission submits that entry of an order barring Selden from serving as an officer or director for a period of five years is the appropriate sanction in this matter.

STATEMENT OF FACTS

Paragraph V of the final judgment provides that, for purposes of the Commission's motion for an officer/director bar, "the allegations of the Complaint shall be accepted as and deemed true by the Court." The Complaint in this matter is about securities fraud and unjust enrichment. Specifically, Selden, the former Chief Executive Officer ("CEO") of Transkaryotic

Therapies, Inc. ("TKT"), committed securities fraud by making, and causing TKT to make, certain false and materially misleading public statements between October 2000 and October 2002 concerning the results of a pivotal clinical trial for TKT's flagship drug, Replagal, and its application for marketing approval in the United States. In addition, Selden unjustly enriched himself by selling company stock during the period his fraudulent misrepresentations buoyed the stock's value.

A. TKT and Selden

TKT was a bio-pharmaceutical company headquartered in Cambridge, Massachusetts. From 1996 through July 2005, TKT common stock was registered with the Commission and traded on the NASDAQ National Market System. On or about July 25, 2005, TKT was acquired by Shire Pharmaceuticals Group, PLC ("Shire") and became a wholly-owned subsidiary of Shire. As a result, TKT is no longer a publicly-traded company and no longer files periodic reports with the Commission. See Complaint, ¶ 11.

Selden, age 49, founded TKT and served as its CEO and as a director from 1988 until his resignation in February 2003. Id. ¶ 10. Currently, Selden is CEO of Network Biosystems, Inc., a privately-held, Delaware corporation. See Network Biosystem's 2007 Annual Report, attached to the Declaration of Richard M. Harper II (hereinafter "Harper Decl.") as Exhibit A. Network Biosystems describes itself as "a development stage biotech/high tech company developing nanotechnology and microfluidics for DNA analysis in clinical, forensic, and genomic applications." See Network Biosystems, Inc. "Home" Webpage, located at http://www.networkbiosystems.com/default.asp and attached to Harper Decl. as Exhibit B. Network Biosystems has developed "broadly enabling technology platforms" in the field of

clinical diagnostics, an area heavily regulated by the U.S. Food and Drug Administration ("FDA"). Id.

B. Replagal and Fabry's Disease

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Back in the spring and summer of 2000, Selden and his former company, TKT, were engaged in efforts to develop a drug to treat patients with Fabry's disease, a rare genetic disorder that primarily affects a patient's kidneys and often causes severe pain. In order to be approved by the FDA, regulations required TKT to prove through controlled clinical studies that its proposed drug, Replagal, would be both <u>safe</u> and <u>effective</u>. In accordance with these regulations, prior to the beginning of clinical studies, TKT submitted clinical study design protocols identifying the specific effects or "end points" that the clinical trials would prove. For Replagal's pivotal clinical study, TKT003, TKT claimed that its primary endpoint would show Replagal's effect on pain. See Complaint, ¶¶ 12-14.

The level of confidence in a statistical result is expressed in terms of probability, often referred to as a "p value." Under statistical principles, the smaller the p value, the greater the level of certainty that the observed effect was not randomly induced, and a p value of 0.05 or less (indicating a 95% level of certainty that the observed effect was not randomly induced) is generally accepted as persuasive evidence of a statistically-significant effect. A p value of higher than 0.05 is not generally accepted as persuasive evidence of a statistically-significant effect and indicates that further analysis is needed to assess whether the drug at issue caused the observed effect. See id. ¶ 15.

In deriving a p value from statistical data for a particular endpoint, the drug company and the FDA agree to a type of statistical analysis to be used. In the clinical study design protocol for TKT003, TKT and the FDA agreed that the primary statistical analysis would be an analysis

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C. The Race With Genzyme For A Seven-Year Marketing Monopoly

Unfortunately for TKT and Selden, they were caught in a drug development race with a formidable competitor. In early 2000, Genzyme, Inc. ("Genzyme") was also in the process of developing its own drug for the treatment of patients with Fabry's disease. Because Fabry's disease is relatively rare (or an "orphan disease"), drugs for treatment of the disease can qualify, under FDA regulations, for "Orphan Drug" status. The relevant "orphan drug" regulations reward companies who undertake the expense and risk associated with research and development of drugs for rare diseases with a marketing exclusion or monopoly for seven years after approval. TKT and Genzyme were competing for this seven-year marketing monopoly in the United States. Whoever received marketing approval from the FDA first would win the race and receive the monopoly. *See* Complaint, ¶ 13.

Consequently, TKT did not have the luxury of time to conduct another study to show a statistically significant clinical benefit for the reduction of pain. Accordingly, in June 2000, Selden had TKT file its Biologics License Application ("BLA") for marketing approval relying on TKT003 despite the fact that its pre-designated primary endpoint analysis failed to show a

statistically significant effect on pain. <u>Id.</u> ¶ 14-16, 13. Genzyme filed a competing application for its drug, Fabrazyme, about one week after TKT's application. Id. ¶ 13.

D. Selden's Suppression of Negative Primary Endpoint Data Results At The ASHG Conference For Medical and Investment Professionals

Even though Selden and TKT submitted Replagal's BLA knowing that its pivotal clinical trial for pain failed to reach its primary end point, beginning in October 2000, Selden began a publicity campaign to promote the drug as if the study had been an unqualified success.

In October 2000, TKT representatives made a presentation concerning TKT003 to medical professionals and investors at a conference sponsored by the American Society of Human Genetics ("ASHG"). TKT's presentation included a slide show, and Selden reviewed and approved each slide in advance. This slide show contained a slide dedicated to an explanation of whether TKT003 had shown a statistically-significant effect on pain. Selden personally decided that TKT's presentation would show p values only from the secondary, supporting analyses, hiding from investors the fact that TKT003's primary efficacy analysis, the AUC analysis, had failed to show a statistically significant effect on pain. As constructed, the slide show misleadingly suggested to investors that pivotal clinical trial for pain (TKT003) had been an unqualified success in demonstrating a statistically-significant effect on pain, a fact which Selden knew to be untrue. <u>Id.</u> ¶¶ 18-20.

E. Selden's Orchestration of TKT's Misleading Statements Suppressing The FDA's Rejection of Pain Data In Its Complete Review Letter

FDA rules require that the agency staff review a BLA and, within six months, either approve the BLA or provide the drug company with a "complete review letter" or "CRL," detailing the reasons why the BLA cannot be approved as submitted. On January 2, 2001, TKT received a CRL from the FDA stating that Replagal failed to demonstrate clinical benefits

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necessary for FDA approval. Specifically, the CRL explained that Replagal's pivotal clinical trial for pain had failed to demonstrate efficacy because its primary endpoint had not demonstrated a statistically-significant effect. In addition, the CRL found that TKT's handling of the study data had introduced "unmeasurable bias" that was "both inappropriate and unacceptable" in a clinical study that was supposed to be double-blind and placebo-controlled. Moreover, the FDA found that there were errors in the design of the study as well as in the collection and handling of the scientific data that caused the data to be inherently flawed. The FDA further "recommend[ed] that [TKT] conduct additional clinical studies and submit the results to [the FDA]." Id. $\P\P$ 21-22.

On the next day, January 3, 2001, after the stock market closed, TKT issued a press release announcing that the FDA had issued its complete review letter. The same day, TKT filed a current report with the Commission on Form 8-K incorporating the press release. Selden actively participated in drafting the release, approved the final version of the release, and was quoted in it. The press release stated that the FDA asked for additional data and that TKT employees were working to provide the information. In addition, the press release stated that data from the pivotal pain efficacy study, TKT003, had been presented at the ASHG conference in October 2000. See Form 8-K Current Report, Exhibit 99.1, January 3, 2001 TKT Press Release, attached to Harper Decl. as Exhibit C ("Data from the pivotal NIH study were presented at the 50th Annual Meeting of the American Society of Human Genetics in October 2000."). This press release was materially misleading because, among other things, it did not disclose that, far from just asking for more information, the FDA had informed TKT that the pivotal study failed to achieve its primary end point and had recommended that TKT conduct additional clinical trials. Further, the press release was materially misleading because it referred investors

to the data presented in the rigged presentation at the ASHG conference, thereby suggesting that efficacy analysis for pain had been an unqualified success. Unbeknownst to investors, the press release referred them to an incomplete dataset that suppressed the fact that the clinical study had failed to show a statistically significant effect for its primary efficacy analysis. Indeed, this suppressed data was the very basis on which the FDA issued the CRL to TKT informing the company that its clinical study failed to show substantial evidence of efficacy for the treatment of pain. <u>Id.</u> ¶¶ 23-24.

F. Selden's Misleading Statements Hiding TKT's Change In Regulatory Strategy For Approval

On April 26, 2001, Selden and several other TKT executives met with the FDA to discuss the complete review letter. At the meeting, the FDA reiterated its position that TKT had not demonstrated that Replagal was effective for pain and that its pain data was uninterpretable. TKT executives then responded that the company would no longer seek FDA approval for Replagal on the basis of effect on pain. The remainder of the meeting focused on other ways in which Replagal might be approved on the basis of effects on renal function. See Complaint, ¶¶ 31-33.

Following the April 26, 2001 meeting with the FDA through May 2002, TKT and Selden continued to make misleading public statements asserting that the FDA merely requested additional data and that the company would provide or had provided the additional data requested. These statements were misleading because, rather than merely requesting additional information, the FDA had explicitly informed TKT that the pivotal study was a failure and had recommended that TKT conduct additional clinical trials. These statements were further misleading because, in response to the FDA's unequivocally negative assessment, TKT had

informed the FDA that it was changing its regulatory strategy to no longer rely upon Replagal's effect on pain as the basis for obtaining FDA approval. Id. ¶¶ 34-35, 40-43.

G. Selden's Misleading Statements To Analysts From Fall 2001 to Spring 2002

From the fall of 2001 through the spring of 2002, Selden expressed unfounded optimism and failed to disclose material negative information about the Replagal application in response to direct inquiries from stock market analysts during quarterly conference calls. The question of whether the FDA had recommended new or additional studies was raised repeatedly during these calls. Each time Selden provided evasive answers which gave the impression that the FDA had not recommended additional studies and that FDA approval on the basis of existing data was likely. Id. ¶ 44. Selden's optimistic statements of progress were materially misleading for several reasons. First, Selden's claims of progress misleadingly omitted the fact that the company had completely changed its regulatory strategy to seek approval on the basis of renal function, rather than pain. Second, despite the change in regulatory strategy, the FDA repeatedly told TKT and Selden that the existing clinical study data submitted to the FDA would be insufficient to support approval of Replagal based upon its effect on renal function. Third, the FDA repeatedly recommended that TKT conduct additional controlled clinical studies, which TKT declined to do. Id. ¶¶ 45-48.

The FDA's Advisory Committee Briefing Book And TKT's October 2, 2002 H. Disclosure Of Failure and Regulatory Strategy Change

In early summer 2002, the FDA scheduled a two-day advisory committee meeting for September 26-27, 2002 to review the competing applications submitted by TKT and Genzyme. Such meetings are typically the last step before an FDA decision on approval, and the meetings involve committee members, guests and advisors. Briefing materials, submitted by the FDA and

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the company submitting the application, are typically posted on the FDA's public website the day before the meeting. Id. ¶ 49.

The FDA's briefing materials, which TKT received before they were made public, were entirely consistent with the FDA's prior statements and recommendations to TKT. The briefing materials harshly criticized TKT's clinical data, particularly the pain data, as well as TKT's methodology and results, and indicated that the FDA staff could not interpret the pain data and could not draw any conclusions with respect to effect on pain. The materials further concluded that the renal and cardiac data did not support approval either. <u>Id.</u> ¶ 50.

Facing the possibility of public disclosure of the FDA's highly critical briefing materials, which would contain specific criticisms of pain data and methodology never previously disclosed to the public, TKT and Selden decided to issue a press release ahead of the FDA's public release of the briefing materials. On October 2, 2002, after the stock market closed, TKT issued a press release announcing that the FDA "indicated that methodological issues made the pain data uninterpretable and that the data supporting the primary pain end point did not support approval." TKT further stated that based on the FDA findings TKT had withdrawn its claim that Replagal was effective against pain as a basis for seeking FDA approval. Id. ¶ 52-53.

The stock market reacted strongly to TKT's disclosure of the major problems with its FDA application for Replagal. On October 3, 2002, TKT shares closed at \$12.75 per share, down 61% from the prior day's close of \$33.25 per share. Id. ¶ 54.

I. Selden's Sale of TKT Shares

During 2001 and the first half of 2002—when he knew that he and TKT had disseminated false and misleading information concerning Replagal to the investing public— Selden sold 90,000 shares of TKT stock at artificially inflated prices. By selling his shares in advance of TKT's disclosure on October 2, 2002, Selden received \$1,664,400 more than he would have received if he had sold those same shares at the closing price of TKT stock after the first day of trading after the negative news had been announced. See Complaint, ¶¶ 58-64.

J. Selden's Heightened Scienter and Consciousness of Guilt

Three particular instances of conduct, found in the complaint and the discovery record, evidence the high degree of Selden's scienter and consciousness of guilt.

The first event concerns Selden's acknowledgement to another TKT executive that public disclosure of TKT's prior failure to disclose the AUC pain results would result in being sued for fraud by TKT's investors. In the weeks leading up to the FDA advisory committee meeting, TKT personnel worked on a presentation that would be used to present Replagal's clinical data to the FDA and the public. As the company prepared this presentation, a heated internal disagreement arose concerning whether TKT should include its pain data. See Deposition Testimony of Thomas Schuetz, M.D., attached to Harper Decl. as Exhibit D, at 146-54. Dr. Thomas Schuetz, M.D., TKT's Vice-President of Clinical Affairs, expressed his view that he "felt quite strongly that [TKT] needed to present [TKT's] pain data." Id. at 11-12, 150. Schuetz knew "the pain data was the primary endpoint in one of the main controlled studies that [TKT] did, and [he] thought that it was really important to present the results of the studies conducted." Schuetz felt strongly about this because he "knew the [FDA] was going to present this data, and . .. if [TKT] simply ignore[d] [its] primary endpoint data, ... the advisory committee would potentially question [TKT's scientists'] credibility as . . . clinician scientists." Id. at 150-51. Selden, on the other hand, "very strongly" opposed including pain data in the advisory committee presentation. Id. at 153. Selden opposed inclusion of pain data because "[h]e said

that it would precipitate a shareholder lawsuit if [TKT] were to present the pain data because we had not ever disclosed the analysis of the AUC result analysis." Id. at 153-54.

The second event concerns an attempt by Selden to suggest lies to Dr. Schuetz about the factual basis for Selden's scienter. During the internal corporate dispute over the inclusion of pain results in the advisory committee presentation, which were "a little heated," Selden called Schuetz into Selden's office where they met alone. See Deposition Testimony of Thomas Schuetz, M.D., Harper Decl., Ex. D, at 154-56. During this meeting, Selden stated that he was unaware that the AUC analysis was not positive, and suggested to Schuetz that Schuetz had told Selden it was positive. Selden also "suggested to [Schuetz] that he was unaware that [TKT] had presented the P value on the slide at the ASHG meeting and that he was unaware of it at the time." Id. 155-56. In fact, Selden's "suggestions" were "preposterous" lies because, at the time TKT created the ASHG presentation in October 2000, Selden himself had personally decided on excluding the primary endpoint (AUC) data from the ASHG presentation after "many" discussions with Schuetz, during which Schuetz advocated for the data's inclusion, and Selden repeatedly balked. <u>Id.</u> 155-56 & 93-100; see also Complaint, ¶ 19. During the subsequent meeting in Selden's office, Schuetz expressly "reminded" Selden that his assertions were "preposterous." Schuetz Depo., Harper Decl., Ex. D at 156.

The third event occurred during an investor conference call on the evening of October 2, 2002 after TKT's disclosure that the FDA viewed the company's pain-related data as "uninterpretable" and that, as a result, TKT had abandoned its claim that Replagal was clinically effective against pain as a basis for seeking FDA approval. During this conference call, Selden stated that TKT had only recently learned of the FDA's position and had just decided to change its approach to the application, when in fact the FDA had been communicating negative

information to TKT since at least January 2001 and TKT had told the FDA in April 2001 that it was changing its regulatory strategy for approval away from pain. See Complaint, \P 3.

APPLICABLE STANDARD FOR DEBARMENT

The Commission bases this motion for an officer/director bar on Section 21(d)(2) of the Securities Exchange Act of 1934 ("Exchange Act") and Section 20(e) of the Securities Act of 1933 ("Securities Act"). These statutory provisions authorize a district court to "prohibit, conditionally or unconditionally, and permanently or for such period of time as it shall determine, any person who violated [the anti-fraud provisions of the Securities Act or the Securities Exchange Act] . . . from acting as an officer or director [of a public company] if the person's conduct demonstrates substantial unfitness¹ to serve as an officer or director" *See* 15 U.S.C. §§ 77t(e) and 78u(d)(2). In deciding whether a person's conduct demonstrates "substantial unfitness to serve as an officer or director," courts typically apply a six-factor test first announced by the Second Circuit in *SEC v. Patel*, 61 F.3d 137, 141 (2d Cir. 1995). *See* SEC v. First Pacific Bancorp, 142 F.3d 1186, 1193 (9th Cir. 1998); SEC v. Robinson, No. 00 Civ. 7452, 2002 WL 1552049, *4 (S.D.N.Y. July 16, 2002). Under this test, the court considers the following factors:

- (1) the "egregiousness" of the underlying securities law violation;
- (2) the defendant's "repeat offender" status;
- (3) the defendant's "role" or position when he engaged in the fraud;
- (4) the defendant's degree of scienter;
- (5) the defendant's economic stake in the violation; and
- (6) the likelihood that misconduct will recur.

¹ On July 30, 2002, Section 305 of the Sarbanes-Oxley Act of 2002 amended the Securities Act and the Exchange Act to remove the word "substantial" from the statutory predicate for an officer/director bar. *See* Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, sec. 305, 116 Stat. 745, 778-79 (2002). The cases cited herein, however, apply the pre-amendment "substantial unfitness" standard.

Patel, 61 F.3d at 141; see also SEC v. Lawbaugh, 359 F. Supp.2d 418, 426 (D. Md. 2005) (quoting *Patel*); SEC v. Global Telecom Services LLC, 325 F. Supp.2d 94, 121 (D. Conn. 2004) (same). As noted by the Second Circuit, a district court need not consider every factor and has "substantial discretion" in deciding whether to impose an officer/director bar. Patel, 61 F.3d at 141.

ARGUMENT

Here, a consideration of the Patel factors reveals that Selden committed egregious securities law violations, that he committed these violations while acting as a director and the company's chief corporate officer, that he acted with a high degree of scienter and with a large economic stake in the violation, and that there is a strong likelihood his misconduct will recur. When considered together, these factors compel the imposition of a five-year bar.

First, Selden's underlying securities law violations were egregious. Selden willfully suppressed Replagal's primary endpoint data from the ASHG conference for the purpose of misleading public investors into believing that Replagal's pivotal NIH clinical trial for pain had been an unqualified success. When the FDA subsequently issued a CRL declaring that Replagal's pivotal clinical trial for pain was a failure, finding that TKT's handling of the study data had introduced "unmeasurable bias" that was "both inappropriate and unacceptable," and recommending that TKT conduct additional clinical studies, Selden continued to orchestrate the deception of investors by drafting and approving a press release stating that the FDA merely asked for additional data, and referring investors to the data presented in the rigged October, 2000 ASHG conference presentation. After TKT informed the FDA in April, 2001 that TKT would no longer seek approval of Replagal based upon its effectiveness on pain, Selden suppressed this additional fact (along with the previous and continuing FDA rejection of pain

data) from investors in multiple public filings with the Commission. It was not until October, 2002, after the FDA informed TKT and Selden that the agency itself would make public its findings with regard to Replagal's pain data that Selden finally approved a TKT release informing public investors that the FDA had "indicated that methodological issues made the pain data uninterpretable[,] that the data supporting the primary pain end point did not support approval," and that TKT had decided to change in regulatory strategy to no longer seek approval based upon pain. By then, Selden had already sold 90,000 shares of TKT stock.

Furthermore, Selden was not just any corporate officer of TKT. He was the company's Chief Executive Officer. The public shareholders of TKT, the owners of the company, entrusted Selden with fiduciary responsibility for leading TKT's operations for their benefit. Instead, Selden abused this trust by suppressing negative material, non-public information about TKT's flagship drug, while at the same time selling his own shares of the company. Although Selden's breach of fiduciary obligation is remarkable in its own right, this fraud should weigh even more heavily on the company's chief corporate executive. As the leader of the corporate organization, Selden had primary responsibility for protecting the interests of TKT's shareholders, above his own, by deed and example. Selden willfully abused that responsibility as if it was not his to bear. There is no attitude more unfitting for the chief corporate officer of a public company.

In addition to being TKT's highest ranking corporate officer, Selden acted with a high degree of scienter. Selden willfully manipulated the ASHG presentation. As CEO of TKT, Selden personally decided to suppress the failed primary endpoint analysis (AUC) despite the fact that Schuetz, TKT's VP of Clinical Affairs, argued for including the failing data in the presentation. *See* Schuetz Depo., Harper Decl. Ex. D, at 11-12, 93-100; Complaint, ¶ 19. Selden also actively participated in drafting and approved a TKT press release misleading investors as to

the FDA's critical findings in its CRL, and further steering those investors back to the rigged ASHG presentation. After TKT informed the FDA in April, 2001 that TKT would no longer seek approval of Replagal based upon its effectiveness on pain, Selden suppressed this additional fact (along with the previous and continuing FDA rejection of pain data) from investors until the FDA finally notified Selden and TKT that it planned to publicly release its findings on Replagal's effectiveness for pain in advance of the advisory committee meeting. Moreover, on October 2, 2002, the day on which TKT finally informed investors of the FDA's criticisms of the pain data and that, as a result, TKT had abandoned its claim that Replagal was clinically effective against pain, Selden misleadingly suggested that the released information was a recent discovery for the self-serving purpose of hiding the fact that he had been making, and causing TKT to make, fraudulent misstatements for over seventeen months. See SEC v. Global Telecom Svcs., 325 F. Supp.2d 94, 121-22 (D. Conn. 2004) (imposing officer/director bar where "wrongful actions occurred over a period of three years, and were not merely isolated incidents").

Selden also acknowledged his high degree of scienter in his comments to Schuetz about including pain data in TKT's presentation to the FDA advisory committee. Selden opposed including the pain data because he knew "it would precipitate a shareholder lawsuit . . . because [TKT] had not ever disclosed the analysis of the AUC result analysis." This comment demonstrates Selden's keen appreciation of the materiality of the information he suppressed. Moreover, during this same "heated" argument between Selden and Schuetz, Selden further revealed his consciousness of guilt when he attempted to suggest the "preposterous" lies (a) that he was not aware of Replagal's failing primary endpoint data, (b) that Schuetz had told him that

the primary endpoint (AUC) had been statistically significant; and (c) that he was unaware that the ASHG presentation had presented statistical *p* values.

Selden's high degree of scienter is not surprising considering the significant financial stake he had in the violations. Selden was a significant shareholder of TKT. TKT's race with Genzyme for "orphan drug" marketing exclusivity in the United State gave Selden a large economic stake in making misleading public statements about TKT's regulatory success in order to buoy the value of TKT's stock. It was this financial stake that allowed Selden to unjustly enrich himself when he sold 90,000 shares of stock while suppressing Replagal's regulatory status and TKT's change in regulatory strategy.

Finally, the record reveals that there is a substantial likelihood that Selden's misconduct will recur. Selden is currently the CEO of Network Biosystems, Inc., a privately-held "development stage biotech/high tech company." See 2007 Annual Report of Network

Biosystems, Inc., Harper Decl., Ex. A. This business is developing products in the field of clinical diagnostics, an area heavily regulated by the FDA. See Network Biosystems, Inc.

Webpage, http://www.networkbiosystems.com/, Harper Decl., Ex. B. If this "development stage" company eventually goes public, Selden will place himself in the same position of public trust and fiduciary responsibility with the same obligations to make ethically sound judgments about when and how to disclose material information about product development and regulatory actions by FDA. To date, Selden has not expressed remorse, or even acknowledged responsibility, for his violations of the federal securities laws. Here, where Selden is actively working toward returning to the same position of responsibility without any acknowledgement of prior wrongdoing, the court has no assurance that Selden will not commit the same breaches of public trust and fiduciary responsibility. Without such assurance, and considering the

egregiousness of Selden's violations, the position of responsibility he held at the time of the violations, and the high degree of scienter he possessed, there is a strong likelihood of future recurrence. See SEC v. Lawbaugh, 359 F. Supp.2d 418, 426 (D. Md. 2005) (finding "strong likelihood of recurrence," where violation "was egregious and indicative of a high degree of scienter, and . . . defendant [had] not expressed remorse."); SEC v. Chester Holdings, Ltd., 41 F. Supp.2d 505, 530 (D.N.J. 1999) (finding "high" likelihood of future misconduct where defendant "has failed to assure this court he will not engage in future violations and . . . is presently involved as a 'Mergers & Acquisitions Business Consultant.'").

CONCLUSION

For the reasons set forth above (and in accordance with the proposed form of order submitted with this motion), the Commission requests that the Court enter an order barring Selden from serving as an officer or director of a public company for a period of five years.

> Respectfully submitted, **SECURITIES AND EXCHANGE** COMMISSION,

By its attorneys,

/s/ R.M. Harper II

Frank C. Huntington (BBO No. 544045) Senior Trial Counsel Richard M. Harper II (BBO No. 634782) Senior Trial Counsel Robert B. Baker (BBO No. 654023) Staff Attorney

² The Commission anticipates that Selden will oppose this motion arguing, among other things, that he is not a "repeat offender" because he has never been charged with another securities violation. The Commission has already taken this factor into account in seeking a five-year rather than a permanent bar. See SEC v. Patel, 61 F.3d at 142 ("a time-limited bar (e.g., a bar of five years) may be sufficient" where all other factors weigh in favor of a bar but defendant is not a repeat offender); SEC v. Chester Holdings, Ltd., 41 F. Supp. 2d at 530 (imposing fiveyear bar on a co-defendant who was not repeat offender).

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Dated: September 2, 2008

CERTIFICATE OF SERVICE

I, Richard M. Harper II, certify that on September 2, 2008, the forgoing Memorandum in Support of Plaintiff's Motion for Entry of Five-Year Bar Order was filed electronically with the Court. Notice will be sent by email to all parties through the Court's electronic filing system, and the filing may be accessed through the Court's system. In addition, the undersigned has caused a paper copy to be served by first-class mail to defendant's counsel of record:

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/s/ R.M. Harper II Richard M. Harper II